K112301(1/3)

JAN - 6 2012

510(k) Summary

Submitter information

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Additional contact person	Karl vom Berge
Contact title	Product Manager
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Submission date

The date of the Traditional 510(k) submission is 8th of August.

Submission information

Trade Name	Zimmer Patient Specific Instruments Planner Zimmer Patient Specific Instruments
Common Name	Knee prosthesis
Classification Name	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Product code	HSX/OOG (21 CFR § 888.3520)

Predicate devices

Predicate Device	
Trade or proprietary or model name	Zimmer Unicompartmental Knee System
510(k) number	K033363
Decision date	01/16/2004
Product code	HSX
Manufacturer	Zimmer, INC.

Predicate Device	
Trade or proprietary or model name	Signature™ Personalized Patient Care System

510(k) number	K110415
Decision date	05/16/2011
Product code	HRY, JWH/OIY, MBH, OOG
Manufacturer	Materialise N.V.

Predicate Device	
Trade or proprietary or model name	Zimmer Patient Specific Instrument System 2.0
510(k) number	K093533
Decision date	02/17/2010
Product code	JWH, MBH
Manufacturer	Materialise N.V.

Device Information

Description of the device

The **Zimmer Patient Specific Instruments System** consists of a software component, **Zimmer Patient Specific Instruments Planner** and a hardware component, **Zimmer Patient Specific Instruments** and is designed to assist the surgeon in the placement of unicompartmental knee replacement components for Unicompartmental High Flex Knee System prosthesis.

Functioning of the device

The Zimmer Patient Specific Instruments System generates a pre-surgical plan based on MRI imaging data using the Zimmer Patient Specific Instruments Planner (software component). The software is then used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Zimmer Patient Specific Instruments are designed and manufactured based on the approved pre-surgical plan. Zimmer Patient Specific Instruments are patient specific templates that transfer the pre-operatively determined positioning of the Unicompartmental Knee Replacement components to the patient intra-operatively, assisting the surgeon in positioning and aligning the actual Unicompartmental Knee Replacement components by guiding and marking cut locations.

Intended use

The **Zimmer Patient Specific Instruments System** is intended to be used as a surgical instrument to assist in the positioning of Unicompartmental Knee Replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The **Zimmer Patient Specific Instruments System** is to be used with Zimmer Unicompartmental High Flex Knee System prostheses families only.

The **Zimmer Patient Specific Instruments** are intended for single use only.

Summary of technological characteristics

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

Performance data

Non-clinical tests

Software validation and accuracy performance testing by means of saw bone models, cadaveric trials and guide deformation verification after sterilization were performed to assess the safety and effectiveness of the device.
These tests verified that the accuracy and performance of the device is adequate to perform as intended.

Clinical data

Non-clinical laboratory testing was performed to determine substantial equivalence.
Testing verified that the accuracy and performance of the device is adequate to perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 6 2012

Materialise N.V.
% Ms. Alexandra Razzhivina
15 Technologielaan
Leuven, 3001 Belgium

Re: K112301
Trade/Device Name: The Zimmer Patient Specific Instruments System 3.0
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prothesis
Regulatory Class: Class II
Product Code: HSX, OOG
Dated: December 16, 2011
Received: December 19, 2011

Dear Ms. Razzhivina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions.(Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112301 (1/1)

Indications for Use

510(k) Number (if known): K112301

Device Name: The Zimmer Patient Specific Instruments System 3.0

Indications for Use:

The Zimmer Patient Specific Instruments System is intended to be used as a surgical instrument to assist in the positioning of Unicompartmental Knee Replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting of the bone provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Zimmer Patient Specific Instruments System is to be used with Zimmer Unicompartmental High Flex Knee System prostheses families only.

The Zimmer Patient Specific Instruments are intended for single use only.

Prescription Use _ X ____ AND/OR Over-The-Counter Use __ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112301